

Application No. 09/970,294  
Amendment dated April 14, 2004  
Reply to Office Action of October 14, 2003

### REMARKS

Applicant amended claims 91, 95, 98, 101, 102, 109, 114-118, 124, 126, 127, 129, 130, and 139-142, and added new claims 146-202 to further define Applicant's claimed invention. Support for claims 146, 147, 149-151, 153, 130, 181, 183, 199, 200, and 202 is found at least in Fig. 21. Support for claims 148, 152, 182, and 201 is found in the specification at least on page 22, lines 4 and 5. Support for claim 154 is found in the specification at least on page 22, lines 3-4 and claims 91 and 95 as originally filed. Support for claim 184 is found in claims 91 and 92 as originally filed. Support for claim 194 is found in claims 130 and 132 as originally filed. Support for new claims 155-176 is found in claims 92-96, 101, 109, 110, 114-126, and 129, respectively, as originally filed. Support for new claims 177, 178, 196, and 197 is found in the specification at least on page 26, lines 6-10. Support for new claims 179 and 198 is found in the specification at least on page 2, lines 22-23 and Figs. 14-15. Support for new claims 185-193 is found in claims 93, 94, 109, and 124-129, respectively, as originally filed. Support for new claim 195 is found in claim 131 as originally filed. No new matter has been added. Claims 146-164 and 167-202 read on at least one of Fig. 21, which the Examiner did not designate as a species in the Restriction Requirement of May 30, 2003, and Species VII, Fig. 6. Claims 165 and 166 read on Species II, Fig. 1D. Applicant consents to the withdrawal of claims 165 and 166 subject to their rejoinder upon allowance of independent claim 154, which is a linking claim that links Species II and VII.

In the Office Action, the Examiner allowed claims 133-135, and 143, and objected to claims 92 and 132 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. Applicant rewrote claim 92 as new independent claim 184. Applicant rewrote claim 132 as new independent claim 194, but without the limitation of intervening claim 131, which Applicant submits is not necessary to the patentability of claim 194. Accordingly, Applicant submits that claims 184 and 194 are allowable.

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Applicant respectfully disagrees with the Examiner's definition of the term "genus claim" in the Office Action. According to the MPEP, "a claim may include two or more of the disclosed embodiments within the breadth and scope of definition (and thus be designated a *generic or genus claim*)." (MPEP § 806.04(e), page 800-41, cols. 1-2 (August 2001)). The difference between a claim that is a "generic claim" and one that is a "genus claim" is that a generic claim "must comprehend within its confines the organization covered in each of the species," *i.e.*, read on all species. (MPEP § 806.04(e), page 800-41, col. 1 (August 2001)). A "genus claim" need only read on at least one species. (See, e.g., MPEP § 806.04(e), page 800-41, col. 2, second full paragraph, lines 3-4 (August 2001)). Accordingly, a genus claim is a subset of a generic claim and may cover fewer than all disclosed species.

According to the MPEP, a "linking claim" is a claim that "links" together inventions otherwise divisible. (MPEP § 809.03, page 800-52, 1<sup>st</sup> col. (August 2001)). The Examiner stated that claims 91, 130, and 133 link all claimed species. (Office Action, page 2, lines 10-12). The "Examiner note" to form paragraph 8.12 states that the paragraph "*must be included in any restriction requirement with at least one linking claim present.*" (See, MPEP § 809.03, page 800-52, 1<sup>st</sup> col. (August 2001)(emphasis added)). Accordingly, Applicant submits that the inclusion of form paragraph 8.12 is appropriate for the present situation and is required by MPEP § 809.03.

The Examiner rejected claims 125 and 126 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses the Examiner's rejection. Claim 125 recites a bioresorbable material that includes "bioresorbable plastics." A bioresorbable plastic is an example of a biologically active chemical agent. Applicant discloses that "[i]n a further step in the manufacture of the screws of the present invention, the screw may be immersed in, or coated with, biologically active chemical agents...." (Specification, page 26, lines 6 and 7; and Fig. 23, box labeled "coat bone screw with biologically active agents"). Applicant submits that one of ordinary skill in the art is familiar with the process of immersing and coating

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bone screws with chemically active agents. Accordingly, Applicant submits that the subject matter of claims 125 and 126 is enabled by Applicant's description.

Applicant respectfully disagrees with the Examiner's contention that the "bioresorbable plastics" recited in claim 125 "are intended to be a substitute for the cortical bone recited by claim 91." (Office Action, page 3, first paragraph). Claim 94, dependent from claim 91, recites the screw being formed "substantially of cortical bone." Claim 124, dependent from claim 94, recites that the screw "further" comprises "a bioresorbable material other than cortical bone." Claim 125, dependent from claim 124, recites that the bioresorbable material includes "bioresorbable plastics." None of claims 91, 94, 124, and 125 recite "bioresorbable plastics" as being a substitute for "cortical bone." Applicant respectfully requests the Examiner to examine claim 125 with the screw as recited in claims 91, 94, and 124 further comprising bioresorbable plastics.

The Examiner rejected claims 95 and 97 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant amended claim 95 to correct the antecedent problem noted by the Examiner. Applicant submits that the rejection of claims 95 and 97 under 35 U.S.C. § 112, second paragraph has been overcome.

The Examiner rejected claims 91, 93-95, 97, 109, 110, 115, 119, 121-123, 130, and 131 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,045,554 to Grooms et al. ("Grooms") in view of U.S. Patent No. 5,088,869 to Greenslade ("Greenslade"). Applicant amended independent claims 91 and 130 to recite that the concavely arcuate portion is "formed from at least a portion of the medullary canal" of a long bone. Greenslade teaches forming concave recesses 27 by using thread rolling dies 39 against body 117. (Greenslade, col. 3, line 46 to col. 4, line 4; Figs. 1 and 5). The recesses formed by rolling the body against the thread dies are not a portion of the medullary canal as recited in claims 1 and 130. Applicant submits that neither Grooms nor Greenslade, whether alone or in proper combination, teach or suggest a screw as recited in Applicant's claimed invention.

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The Examiner also rejected claims 98-101 under 35 U.S.C. § 103(a) as being unpatentable over Grooms and Greenslade, further in view of U.S. Patent No. 6,030,162 to Huebner; claim 118 under 35 U.S.C. § 103(a) as being unpatentable over Grooms and Greenslade, further in view of U.S. Patent No. 6,043,344 to Schenk; claim 120 under 35 U.S.C. § 103(a) as being unpatentable over Grooms; and claims 124, 127-129, and 139-142 under 35 U.S.C. § 103(a) as being unpatentable over Grooms and Greenslade, further in view of U.S. Patent No. 6,048,204 to Klardie et al. Applicant submits that the rejections over claims 98-101, 118, 120, 124, 127-129, and 139-142 are rendered moot at least because they depend from an allowable independent claim, or claims dependent therefrom.

The Examiner rejected claims 125 and 126 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,275,601 to Gogolewski et al. ("Gogolewski"). Applicant respectfully traverses the Examiner's rejection. Dependent claim 94, from which claim 125 indirectly depends, recites a screw formed "substantially of cortical bone of a single cortical thickness." Gogolewski teaches a screw made of a resorbable polymer. (Gogolewski, col. 3, lines 26-28). Gogolewski does not teach or suggest a screw formed substantially of cortical bone as claimed in claim 94. Gogolewski also does not teach or suggest a screw formed of cortical bone and comprising a bioresorbable plastic as claimed in claim 125.

New independent claim 154 recites a screw formed of cortical bone having an enlarged portion configured to prevent the trailing end of the screw from passing through the screw hole of an implant, the enlarged portion including "a concavely arcuate portion in said cross section transverse to the mid-longitudinal axis of said shaft." Applicant submits that none of the art cited by the Examiner teaches or suggests a screw as recited in claim 154.

The Examiner provisionally rejected claims 91-95, 97-101, 109, 110, 114, 115, 118-129, and 139-142 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8, 16-18, 21, 22, 25-34, and

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139-142 of copending Application No. 09/970,241 ("the '241 application"). Applicant respectfully traverses the provisional rejection.

The third sentence of 35 U.S.C. § 121 prohibits the Examiner from using an application filed as a result of a restriction requirement from being used as a reference against any divisional application. (See, e.g., MPEP § 804.01, page 800-30, col. 1, second paragraph, lines 4-9 (August 2001)). The present application is a divisional application of Application No. 09/566,055 ("the '055 application") and was filed as a result of the Restriction Requirement of August 17, 2001 in the '055 application (a copy of which is attached for the Examiner's convenience). The present application includes claims 91-135 that were restricted out of the '055 application as being claims drawn to a non-elected species. Claims 91-135 of the '055 application correspond to claims 91-135 of the present application.

The '241 application is also a divisional application of the '055 application and was filed as a result of the August 17, 2001 Restriction Requirement in the '055 application. The '241 application includes claims 1-37 and 136-138 that were restricted out of the '055 application as being drawn to a non-elected species, *i.e.*, the species of Fig. 17. Thus, pursuant to the third sentence of 35 U.S.C. § 121, the claims of the present application and those of the '241 application cannot be used as a reference against each other. Accordingly, Applicant respectfully submits that the Examiner's provisional double patenting rejection is precluded by 35 U.S.C. § 121.

Further, in the Restriction Requirement of May 30, 2003 in the '241 application, the Examiner identified the subject matter of Figs. 17 and 21 as corresponding to patentably distinct species. Independent claims 91, 130, and 133 of the present application recite a screw or a method for forming a screw that has a thread having "a concavely arcuate portion and a convexly arcuate portion opposite said concavely arcuate portion." This feature is shown, for example, in Fig. 21, but is not shown in Fig. 17. Independent claim 1 of the '241 application recites a screw having a trailing end "configured to cooperatively engage at least a portion of the screw hole of the implant so as to prevent said screw from linear motion along the mid-longitudinal axis of

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said shaft in a direction opposite to the direction of insertion." This feature is shown, for example, in Fig. 17, but is not shown in Fig. 21. Accordingly, Applicant submits that independent claims 91, 130, 133 of the present application contain a feature that is patentably distinct from the subject matter of independent claim 1 of the '241 application. Applicant submits that the provisional double patenting rejection has been overcome.

Applicant submits that independent claims 91, 130, 154, 184, and 194 are patentable and that dependent claims 92-95, 97-101, 109, 110, 114, 115, 118-129, 131, 132, 139-142, 146-153, 155-183, 185-193, and 195-202 dependent from one of independent claims 91, 130, 154, 184, and 194, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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